


Product Brochure-FFP2 mask

DCI 3D MASK
CE 2163 FFP2 NR
EN149:2001 + A1:2009
KOREAN
SOMETHING DIFFERENT
FILTERING HALF MASK



DCI INDUSTRY CO.,LTD
South Korea
info@dc-industry.com
+82 10 9208 7110
dc-industry.com

Description of the product

MAMUFACTURER NAME :	DCI INDUSTRY CO.,LTD
MAMUFACTURER ADDRESS :	26-20 826 beon-gil, Seobu-ro, Jillye-myeon, Gimhae-si, Gyeongsangnam-do, South Korea
PRODUCT TYPE :	Particle Filtering Half Mask
PPE REGULATION :	(EU)2016/425-catalog III
APPICABLE STANDARDS :	EN149:2001+A1:2009
PERFORMACE CLASSIFICATION :	FFP2 NR (CE2163)-Certification No : 2163-PPE-1977
MODEL IDENTIFICATION :	DCI 3D MASK (DOCTOR SOOMEASY) DCI 3D MASK means that a mask in form of three folds vertically made by DCI INDUSTRY. DOCTOR SOOMEASY means that a mask developed by 3 doctors and easy to breathing. (the words " SOOM" means "Breathing" in Korean language ")
DATE AND REVISION CONTROL :	13 JANUARY 2021 VERSION 0
PRODUCT IMAGE	
	
SUNMITTED BY NAME:	CHOI JONG HWAN
SUNMITTED BY DATE:	13-Jan-21

Packaging Marking Detail

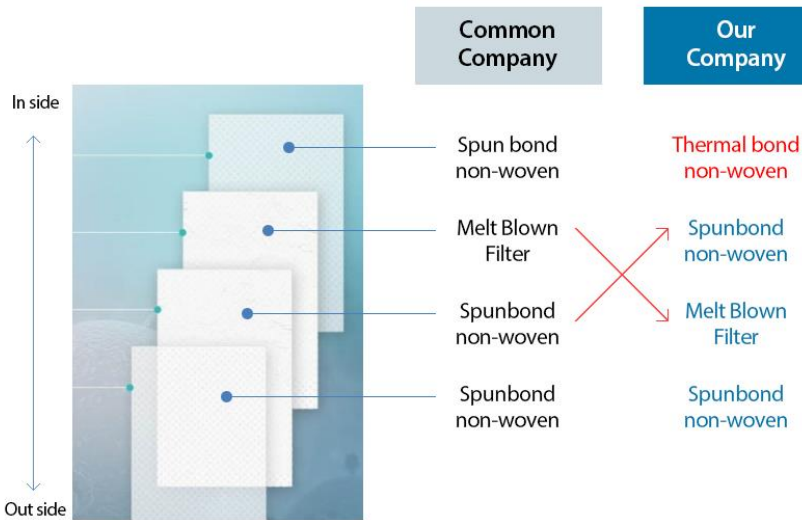


Packing :	Individual packaging	1 pcs
	In-box charge quantity	50 pcs,
	Carton charge quantity	500 pcs
	Pallet loading quantity	14,000 pcs

Design Concept.



Special 4-layer(TSMS) structure mask

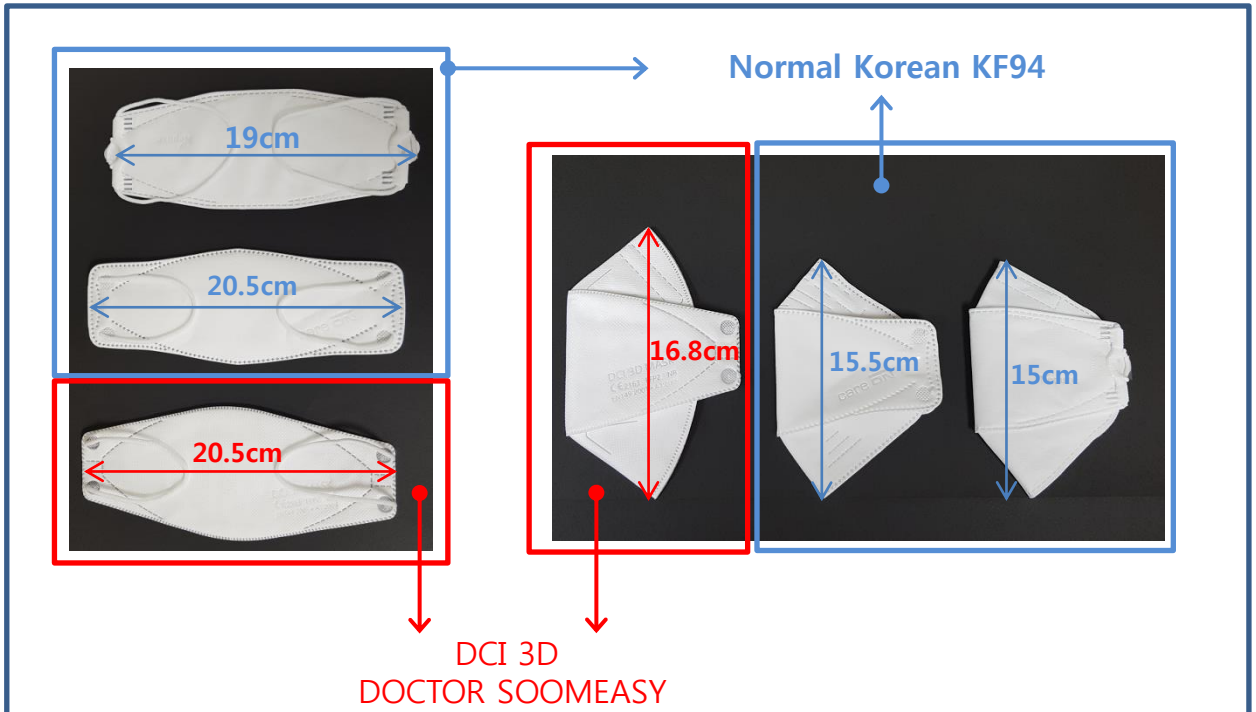


Inhaling should be easier than exhaling.

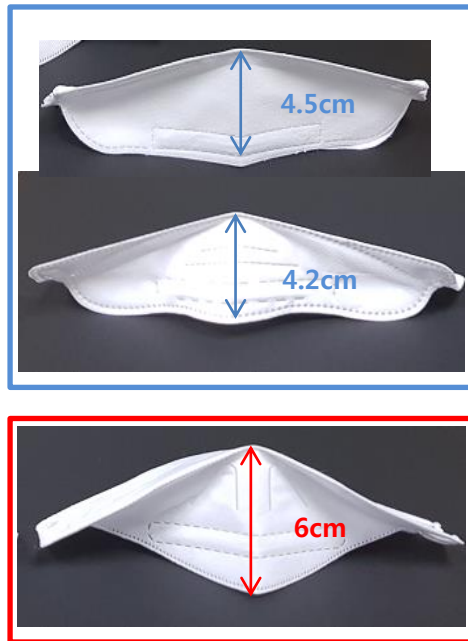
The static electricity of the MB filter should be stored as long as possible.

Since the static electricity is so vulnerable to moisture, the MB filter must be located far away from the mouth.

Size Comparison (Real measured Data)

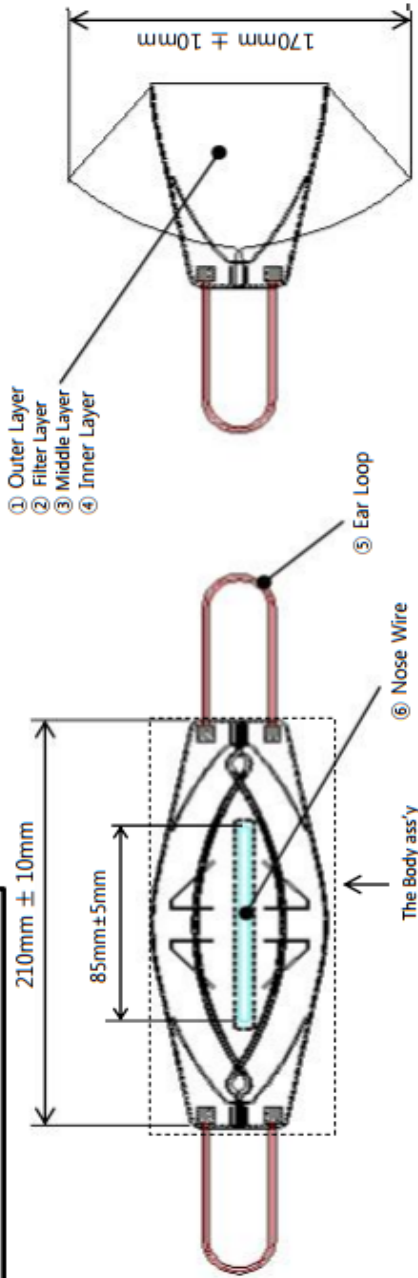


DIFFERENT SIZE MAKE DIFFERENT VOLUME



Design and Manufacturing Drawing

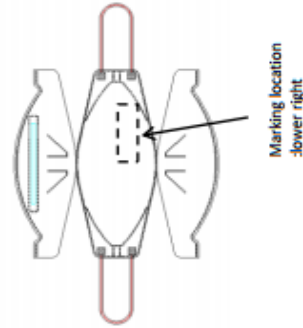
This drawing is the property of DCI Industry Co., Ltd. Protected by applicable laws and regulations. Therefore, unauthorized reproduction or disclosure is prohibited.



Component Details

no	Component	Name/ Material	Class	Length	Weight(g) ±10%	Quantity
1	Outer Layer	PP Spunbond non-woven	50gsm		1.6	1
2	Filter Layer	M8 filter	35gsm		1.1	1
3	Middle Layer	PP Spunbond non-woven	25gsm		0.8	1
4	Inner Layer	Thermal bond non-woven	25gsm		0.8	1
5	Ear Loop	nylon/ polypropylene	3mm	170±10mm	0.25	2
6	Nose Wire	Polypropylene coated wire	4mm	85±5mm	0.4	1

Design



MANUFACTURING PROCESS

1. Input of the Fabric :
Middle Layer, Filter layer, and Inner Layer are placed in this order on the outer Layer at the bottom.
2. Body ass'y Forming
The nose wire is inserted between the Middle Layer and the Filter Layer, and The body is fused by ultrasonic welding.
3. Ear Loop Attachment
The ear loop is fused on the outer layer of the body by ultrasonic welding

DWG.NO	DWG-2020-3D-001
TITLE	DCI 3D MASK (DOCTOR SOOMEASY)
TYPE	Filtering Half Mask (FFP II)
MANUFACTURER	DCI INDUSTRY CO.,LTD (SOUTH KOREA)
Drw/Dsn	2020.09.01 Lee Jin Su

Note

1. Longest length horizontally when the mask body is folded horizontally 210 ± 10mm
2. Longest length vertically folded vertically so that left and right symmetry 170 ± 10mm.
3. The length of the Ear Band excluding the junction after removing from the body 170 ± 10mm)
4. Product quality not specified must meet the following standard : EN149 :2001+A1:2009

Test Result of Filtering Efficiency

FFP2 grade, but satisfies FFP3 grade

According to the reported results, the product meets the limits for FFP2 classification.

Penetration of filter material: Sodium Chloride Testing

Condition	No. of Sample	Sodium Chloride Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	36	0,05	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1 FFP2 and FFP3 classes.
(A.R.)	37	0,14		
(A.R.)	38	0,15		
(S.W.)	1	0,18		
(S.W.)	2	0,13		
(S.W.)	3	0,17		
(M.S. T.C.)	10	0,20		
(M.S. T.C.)	11	0,34		
(M.S. T.C.)	12	0,29		

Conditioning: (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

95 L/min = 1,6 dm³.sn⁻¹



Penetration of filter material: Paraffin Oil Testing

Condition	No. of Sample	Paraffin Oil Testing 95 L/min max (%)	Requirements in accordance with EN 149:2001 + A1:2009	Result
(A.R.)	39	0,14	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Filtering half masks fulfill the requirements of the standard EN 149:2001 + A1:2009 given in 7.9.2 in range of the FFP1 FFP2 and FFP3 classes.
(A.R.)	40	0,21		
(A.R.)	41	0,18		
(S.W.)	4	0,21		
(S.W.)	5	0,20		
(S.W.)	6	0,22		
(M.S. T.C.)	13	0,60		
(M.S. T.C.)	14	0,78		
(M.S. T.C.)	15	0,64		

Conditioning: (M.S.) Mechanical Strength
(T.C.) Temperature Conditioning
(A.R.) As Received, original
(S.W.) Simulated wearing treatment

Please refer to the separate test report provided by the manufacturer for other detail test result.

User Information

DECLARATION

Supply of User Information

Declaration Number : DCI-2020108-002

The Manufacture : **DCI INDUSTRY CO.,LTD**

Company Address : 909-13 Seobu-ro 826beon-gil, Jillye-myeon, Gimhae-si, Gyeongsangnam-do, South Korea.

Factory Address : 26-20, Seobu-ro 826beon-gil, Jillye-myeon, Gimhae-si, Gyeongsangnam-do, South Korea.

Provides information about PPE's user information as follows

Product : Particle Filtering Half mask

Product name : DCI 3D MASK (DOCTOR SOOMEASY MASK)

Intended use of the product

This product is intended to be used as a single shift use particle filtering half masks for protection against solid and liquid aerosols.

Instructions

- See information supplied by the manufacturer
- Place the particle filtering mask onto the face to cover both nose and chin.
- Hold the particle filtering mask with nose wire section up, cover your nose and mouth.
- Adjust the nose area by pressing the nose wire on the bridge of the nose with your fingers.
- Cover the entire particle filtering mask by both hands and adjust the mask to stick to the face well.

Caution

- Single shift use only (NR)
- Do not use a towel or a facial tissue under the particle filtering mask.
- Do not use if inside of the particle filtering mask is contaminated.
- Do not wash the particle filtering mask.
- Do not deform the shape of the particle filtering mask.
- Avoid keep the particle filtering mask when wearing it.
- Stop using the particle filtering mask and consult with a doctor in case of any difficulty in breathing while using the particle filtering mask especially for pregnant women, patients with respiratory and cardiovascular disease, children and elderly.
- Do not use in a closed place with less than 18% oxygen concentration.
- As facial hair reduce the protection offered it is recommended that these respirators are used by clean shaven personnel only.
- Do not use for protection against gases.
- Do not remove whilst in contaminated area.

Packing unit : 1pcs

Expiry Date : 36 months after manufacturing date **Lot No :** Indicated separately

Storage : at room temperature (1~30°C) in dry(maximum relative humidity of storage condition is 70%) ventilated and noncorrosive atmosphere.

Components : Outer Layer, Inner Layer, Filter, Middle Layer(non-woven fabric),
Nose wire (polypropylene coated wire), Ear Loop (Polyurethane string)

Standard : EN149:2001+A1:2009

Classification : FFP2 NR

C/S : +82-55-902-7110 **Email :** info@dci-industry.com

This declaration is issued under the responsibility of the manufacture.

2021.01.08



DCI INDUSTRY Co., Ltd

Jong-Hwan Choi

CEO

Conforms to EN149:2001+A1:2009

CE 2163 FFP2 NR

Product conforms to the requirements of **Regulation(EU) 2016/425** of European Parliament of the Council as Personal Protective Equipment (**PPE**) EU Type Examination(Module B and Module C2) certificate issued by Universal Certification and Surveillance Services Trade Co. in Turkey [N.B No.2163]

CE Certification

UNIVERSAL



EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1977

Respiratory protective devices, filtering half masks to protect against particles manufactured by

DCI INDUSTRY CO., LTD.

909-13, Seobu-ro, Jillye-myeon, Gimhae-si, Gyeongsangnam-do, South Korea

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices -
Filtering Half Masks to Protect Against Particles -
Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Single use particle filtering half mask for protection against solid and liquid aerosols, is a folding type, 4 layered, without valve, ear straps and adjustable nose bar.

Model: DCI 3D MASK

Classification: FFP2 NR

For more details, refer technical evaluation report provided to the manufacturer, dated 04.02.2021 and number 2163-KKD-1977.

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation.

This certificate is initially issued on **04/02/2021** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director

ie validity with the QR code



Splash Test Result. 1/2




Test Report

No.T32120240645SN

Date: Apr 16, 2021

Page 1 of 2

DCI INDUSTRY CO., LTD.

909-13, SEOBU-RO, JILLYE-MYEON, GIMHAE-SI, GYEONGSANGNAM-DO, KOREA

The following samples were submitted and identified by/on behalf of the client as:

DCI 3D MASK (DOCTOR SOOMEASY)

Case No. : CA321202439609
 SGS Reference No. : AYUC21-00013
 Lot No. / Batch Code : NOT PROVIDED
 Sample Description : WHITE MASK
 Manufacturer : DCI INDUSTRY CO., LTD.
 Quantity Submitted : 100 PCS
 Country of Origin : SOUTH KOREA
 Sample Receiving Date : MAR 26, 2021
 Testing Period : MAR 26, 2021 – APR 16, 2021

Test Requested	Conclusion
Resistance to penetration by synthetic blood (ASTM F1862/F1862M-17)	PASS

***** FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) *****

Signed for and on behalf of
SGS Hong Kong Ltd.


 Au Kam Chi, Gigi
 Technical Manager

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.



Splash Test Result. 2/2



Test Report

No.T32120240645SN

Date: Apr 16, 2021

Page 2 of 2

Test Results:

Resistance to penetration by synthetic blood ASTM F1862/F1862M-17

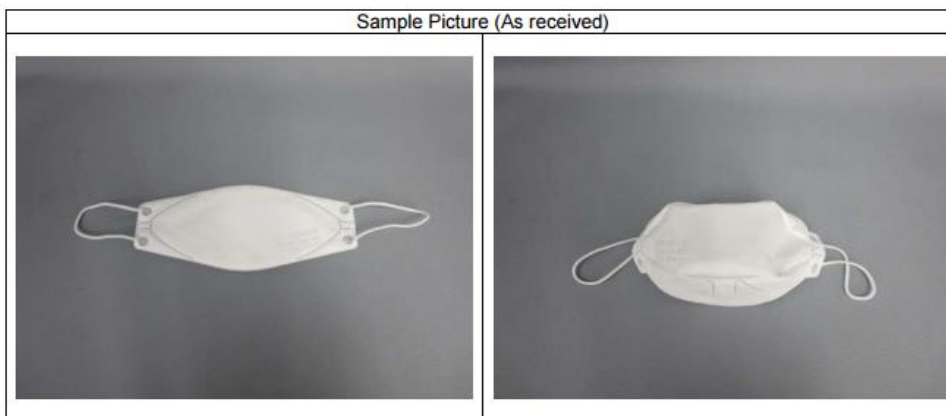
Test Side : Outside
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Condition : 21±5°C and 85±10% R.H.
 Test Pressure : 120 mmHg → LEVEL 2
 No of Test Specimen Tested : 32
 No of Test Specimen Passed : 31

Test Specimen #	Synthetic Blood Penetration
1-30, 32	None Seen
31	Yes

Note:

An acceptable quality limit of 4,0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

Sample Photo:



SGS authenticate the photo on original report only

*** End of Report ***

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

FDA Certification



2020 FDA CERTIFICATE

This certifies that:

DCI INDUSTRY CO.,LTD
909-13 Seobu-Ro, Jillye-Myeon
Gimhae Chungcheongnamdo, 50876, Republic of Korea

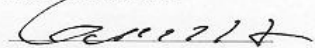
is registered as Medical Device Establishment and has listed the following medical device with the U.S. Food and Drug Administration in accordance with Title 21, 807 et seq. of the U.S. Code of Federal Regulations, such registration and listing having been verified as currently effective on the date hereof by ILRS:

Product: **DCI 3D MASK**
DCI KIDS FACE MASK

Operator Number: **10078514**
DUNS number: **69-550-4003**
Product Code: **LYU**
Listing Number: **D423231**
U.S. Agent for FDA: **ILRS (International Licensing Research Solutions, LLC)**

This certificate confirms that such registration having been verified as effective by ILRS as of the date hereof, and ILRS will support that such registration remains effective upon request and presentation of this certificate until December 31, 2021, unless the validity of registration has been expired after issuance of this certificate. ILRS makes no other representations or warranties, nor does this certificate make any representations or warranties to any entity other than the named certificate holder, for whose sole benefit it is issued. ILRS takes no liability to any entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. ILRS is not affiliated with the U.S. Food and Drug Administration.

ILRS
3660 Wilshire Blvd Suite 320, Los Angeles,
California, 90010, USA


Eddy K
Chairman of ILRS

Dated: OCT. 10. 26



FDA Certification



2020 FDA CERTIFICATE

This certifies that:

DCI INDUSTRY CO.,LTD
 909-13 Seobu-Ro, Jillye-Myeon
 Gimhae Chungcheongnamdo, 50876, Republic of Korea

is registered as Medical Device Establishment and has listed the following medical device with the U.S. Food and Drug Administration in accordance with Title 21, 807 et seq. of the U.S. Code of Federal Regulations, such registration and listing having been verified as currently effective on the date hereof by ILRS:

Product: **DCI 3D MASK**
DCI KIDS FACE MASK
 Operator Number: **10078514**
 DUNS number: **69-550-4003**
 Product Code: **QKR**
 Listing Number: **D423233**
 U.S. Agent for FDA: **ILRS (International Licensing Research Solutions, LLC)**

This certificate confirms that such registration having been verified as effective by ILRS as of the date hereof, and ILRS will support that such registration remains effective upon request and presentation of this certificate until December 31, 2021, unless the validity of registration has been expired after issuance of this certificate. ILRS makes no other representations or warranties, nor does this certificate make any representations or warranties to any entity other than the named certificate holder, for whose sole benefit it is issued. ILRS takes no liability to any entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. ILRS is not affiliated with the U.S. Food and Drug Administration.

ILRS

3660 Wilshire Blvd Suite 320, Los Angeles,
 California, 90010, USA

Eddy K
 Chairman of ILRS

Dated: OCT. 10. 26



ISO13485 Certification

NTREE

Certificate of Registration

DCI INDUSTRY Co., Ltd.

909-13, Seobu-ro, Jillye-myeon, Gimhae-si, Gyeongsangnam-do, Republic of Korea

has been approved by NTREECERT Co., Ltd. to the following medical devices quality management system standards :

ISO 13485:2016

The scope of medical devices quality management system is applicable to :

Development, Manufacturing and Sales of Dental Mask

Valid Date

From 03 November 2020 To 02 November 2023

Former Certificate : 03 November 2020

Certificate No. : NTM-0039 Date of last Issue : 03 November 2020

Rev. 00



President of NTREE Cert



www.ntreecert.kr
NTREE Certification Co.,Ltd



30, Pajangcheon-ro 44beon-gil, Jangan-gu, Suwon-si, Gyeonggi-do, Republic of Korea

Certificate of Business Registration



(1 / 1)

발급번호 Issuance number	사업자등록증명 Certificate of Business Registration (법인사업자) (Corporate Taxpayer)	처리기간 Processing time
7594-960-6725-864		즉시 Immediately
상호 (법인명) Name of company	주식회사 디씨아이인더스트리 DCI INDUSTRY CO.,LTD	
사업자등록번호 Business registration number	297-86-01927	
성명 (대표자) Name of representative	최종환 CHOI JONG HWAN	
주민(법인)등록번호 Resident(Corporation) registration number	195511-0246235	
사업장소재지 Business Address	경상남도 김해시 진례면 서부로 909-13 909-13, Seobu-ra, Jillye-myeon, Gimhae-si, Gyeongsangnam-do, Republic of Korea	
개업일 Date of business commencement	2020년(Year) 07월(Month) 01일(Day)	
사업자등록일 Date of business registration	2020년(Year) 07월(Month) 01일(Day)	
업태 Business type	제조업/도소매 Manufacturing/Wholesale and retail trade	
종목 Business item	마스크 Face Mask 기계부품 Wholesale of electrical machinery and related materials	
공동사업자 Joint business owner	성명(법인명) Name(Name of company)	주민(사업자)등록번호 Resident(Business) registration No.
	해당사항 없습니다 (No Data)	

위와 같이 증명합니다.

I certify that above information is true and correct to the best of my knowledge and belief.
 ※ 위 내용은 발급일 현재 상황으로서 추후 변경될 수 있습니다.
 This information is true as of the issuance date of this certification and but maybe subject to change in the future.

접수번호 Receipt No.	502082209299
담당부서 Department	민원봉사실 Taxpayer Service Center
담당자 Staff in Charge	김미정 Kim Mi jeong
연락처 Telephone No.	+082-55-320-6224

2020년 11월 3일
Year Month Day

김해세무서장 (인)
Head of Gimhae District Tax Office



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Thanks!!

- Our video is provided separately-



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